

REMARKS

Claims 1-23 are pending in the present application. Claims 5-9 are herein amended. Claims 1-4 and 10-14 are herein cancelled without prejudice. No new matter has been added.

Applicants' Response to Claim Rejection Under 35 U.S.C. § 112

Claims 5-9 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

It is the position of the Office Action that claim 5 does not set forth the exact procedural steps that must be performed in order to achieve the claimed method. In response, Applicants herein amend claim 5 in order to recite an “administering” step. Support for this amendment can be found at least at page 14, line 10.

Furthermore, Applicants herein amend claims 5-9 in order to more clearly recite the claimed method. Support for the claim amendments may be found within Applicants' specification, as originally filed. For example, support for the claim amendments may be found in paragraphs [0006] and [0018]. Favorable reconsideration is earnestly solicited.

Applicants' Response to Claim Rejection Under 35 U.S.C. §102

Claims 5-9 were rejected under 35 U.S.C. § 102(b) as being anticipated by Allison et al. (WO 02/15892).

Allison discloses the combination of an insulin secretion enhancer or salt thereof and at least one of the active ingredients selected from the group consisting of HMG-CoA reductase

inhibitors or salt thereof and an ACE inhibitor or a salt thereof, which may include a pharmaceutically acceptable carrier.

The method disclosed by Allison is a “method for the prevention, delay of progression or treatment of a disease and disorder which may be inhibited by the enhancement of insulin secretion, the inhibition of an ACE inhibitor and/or by the inhibition of HMG-CoA reductase comprising administering to a ...man, in need thereof jointly therapeutically effective amounts of at least two therapeutic agents selected from the group consisting of the active ingredients: (a) insulin secretion enhancer...(b) at least one of the active ingredients selected from the group consisting of: (i) HMG-CoA reductase inhibitors...and (b) ACE inhibitors.” See Allison, page 10, line 15. The combination disclosed by Allison is directed at promoting the secretion of insulin from pancreatic β -cells.

Applicants respectfully submit that Allison does not disclose or suggest treating a disorder associated with the activation of γ -secretase. While Applicants’ claimed method and the method of Allison both use pitavastatin, Applicants respectfully submit that Allison does not disclose a method of treating a disorder associated with activation of γ -secretase or administering an effective amount of pivatastatin to a patient in need of inhibiting the γ -secretase activity in a nerve cell. Therefore, Allison does not disclose or suggest the embodiments as claimed. The claimed method is directed towards a different chemical mechanism to bring about a different result as compared to Allison—the inhibition of the formation of an active complex of γ -secretase and thus the treatment of a disorder associated with the activation of γ -secretase. Additionally, Applicants respectfully submit that the claimed method is not a discovery of an

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inherent *property* of pitavastatin, but rather the discovery of a new, non-obvious unexpected *use* of pitavastatin. Therefore, Applicants respectfully submit that Allison does not anticipate the claimed embodiments. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). Favorable reconsideration is earnestly solicited.

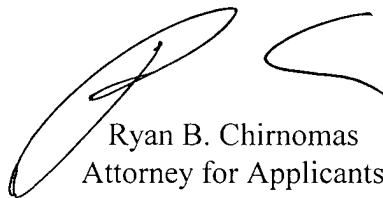
For at least the foregoing reasons, the presently claimed method distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

Should the Examiner deem that any further action by Applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned agent.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP

A handwritten signature in black ink, appearing to read 'Ryan B. Chirnomas', is written over the printed name and title.

Ryan B. Chirnomas
Attorney for Applicants
Registration No. 56,527
Telephone: (202) 822-1100
Facsimile: (202) 822-1111

RBC/BKM/bam